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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09.667,365	09.21.2000	Masashi Suganuma	12155-002001	9752

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07.14.2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/667,365

Applicant(s)

SUGANUMA ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86 is/are pending in the application.
- 4a) Of the above claim(s) 1-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81-86 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-86 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-949)
- 3) ☐ Interview Summary (PTO-413) Paper No. _____
- 4) ☐ Notice of Informal Patent Application (PTO-150)

DETAILED ACTION

1. The amendment filed April 30, 2003 in Paper No. 16 is acknowledged and has been entered.
2. Claims 1-86 are pending in the application. Claims 1-80 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.
3. Claims 81-86 are currently under prosecution.

Response to Amendment

4. In the remarks, Applicants have requested examination of "the unelected species in the subject application" (page 2, paragraph 2). In reply to Applicants' remarks, the restriction requirement set forth in the Office action mailed May 3, 2002 (Paper No. 10) required Applicants to elect a single invention, or group of claims and a single polypeptide to which the claims would be drawn during examination. Applicants complied with this requirement in the responses filed July 18, 2002 (Paper No. 12) and September 23, 2002 (Paper No. 14) by electing the invention of group 665, or claims 81-86, insofar as the claims are drawn to a method for screening for compounds capable of inhibiting a cell cycle arrest checkpoint, wherein said method comprises contacting a cell with a polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 1897. In the preceding Office action, Applicants received an action on the merits for the elected invention. Applicants are advised to file a divisional application or

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 81-86 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in section 5 of the previous Office action mailed December 31, 2002 (Paper No. 15).

Applicants have traversed these grounds of rejection arguing that the disclosure would enable the skilled artisan to use the claimed invention with a reasonable expectation of success without need of performing an additional and undue amount of experimentation.

Applicants' arguments have been carefully considered but not found persuasive. As stated in the previous Office action, the specification does not disclose whether the peptide of SEQ ID NO: 1897, or any other polypeptide comprising SEQ ID NO: 1897 is capable of acting as a substrate of Chk2. Because the specification does not provide guidance supporting the assertion that a polypeptide of SEQ ID NO: 1897 would be expected to act as a substrate of Chk2, the skilled artisan could not use the claimed invention with a reasonable expectation of success without first having to determine if a polypeptide comprising SEQ ID NO: 1897 can be used as a positive control, or is, in fact, phosphorylated by Chk2 kinase and inhibits or abrogates the G2 checkpoint. In view of the large number of peptides tested that are not expected to be capable of inhibiting or abrogating the G2 checkpoint and in view of the lack of guidance and direction that would instruct the artisan to know whether a polypeptide comprising SEQ

could whether a polypeptide comprising SEQ ID NO: 1897 would be reasonably expected to act as a substrate of Chk2. Without knowledge of the certainty or

probability that a polypeptide comprising SEQ ID NO: 1897 is a substrate of Chk2 kinase, the skilled artisan could not have a reasonable expectation of success in practicing the claimed invention without the need to perform additional, undue experimentation. Accordingly, the grounds of rejection of claims 81-86 set forth in the previous Office action are maintained.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.

Examiner

Art Unit 1642

slr

July 9, 2003

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